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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/495,861	02/02/2000	Martin J Page	1430-234	5381

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EXAMINER
GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/16/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 9/4/01

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 48-85 is/are pending in the application.
Of the above, claim(s) 50-53,56,57,60-63,66,67 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☑ Claim(s) 48,49,54,55,58,59,64,65,68-85 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☑ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☑ received in Application No. (Series Code/Serial Number) ONE OF THE PARENT APPLICATIONS.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☑ Notice of Reference Cited, PTO-892
☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☑ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

DETAILED ACTION

1. Applicant's amendment, filed 9/4/01 (Paper No. 7), has been entered.
Claims 48, 49, 58, 59 and 61 have been amended.
Claims 79-85 have been added.

Claims 48-85 are pending.

Claims 1-47 have been canceled previously.

Applicant's election of cancer where the cancer is non-Hodgkins lymphoma in Paper No. 7 is acknowledged.

Claims 48, 49, 54, 55, 58, 59, 64, 65 and 68-85 as they read on the elected invention are under consideration in this application.

Claims 50-53, 56, 57, 60-63, 66 and 67 have been withdrawn from consideration by the examiner 37 CFR 1.142(b), as being drawn to a nonelected species;

2. Applicant should amend the first line of the specification to update the status (and relationship) of the priority documents. For example, USSN 08/475,607 is now abandoned.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

4. The Abstract of the Disclosure is objected to because it does not adequately describe the claimed invention. Correction is required. See MPEP 608.01(b).

5. Formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84.
Please see the enclosed form PTO-948.

Applicant is reminded to change the Brief Description of the Drawings in accordance with these changes, if appropriate.

6. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.
Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.
Appropriate corrections are required

7. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.
(b) Cross-References to Related Applications.
(c) Statement Regarding Federally Sponsored Research or Development.
(d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
(e) Background of the Invention.
    1. Field of the Invention.
    2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).
(h) Detailed Description of the Invention.
(I) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing (see 37 CFR 1.821-1.825).

Applicant is required to amend the specification to comply with these guidelines.

8. The following is a quotation of the first paragraph of 35 U.S.C. § 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 48, 49, 54, 55, 58, 59, 64, 65 and 68-85 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

The specification as originally filed does not provide support for the invention as now claimed:

The recitation of elected claims 48, 49, 54, 55, 58, 59, 64, 65 and 68-85 is not readily apparent in the specification as filed.

Applicant's reliance on generic disclosure and possibly a single or limited species do/does not provide sufficient direction and guidance to the "features" currently claimed. It is noted that a generic or a sub-generic disclosure cannot support a species unless the species is specifically described. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05.

It appears that applicant has expanded the Examples of CAMPATH-1 into a new genus or subgenus.

Also, the written description of specific steps of the claimed methods (e.g. claims 48, 58) as well as certain limitations (e.g. "greater than five months", "undergoes multiple passages", "obtained from a source other than directly from an animal source", etc. etc. etc.) are not readily apparent in the specification as filed, particularly as they read on the genus/subgenus currently recited.

Obviousness is not the standard for the addition new limitations to the disclosure as filed.

Applicant's amendments, filed 10/13/00 (Paper No. 3) and 9/4/01 (Paper No. 7) asserts that no new matter has been added and directs support to certain passages of the instant specification.

Applicant is invited to provide clear written support for the claims as currently recited.

The specification as filed does not provide a sufficient written description of the pending claims for the reasons above. The specification does not provide sufficient blazemarks nor direction for the instant methods encompassing the above-mentioned "limitations" as they are currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02 and 2163.06

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 48, 49, 54, 55, 58, 59, 64 and 65 are rejected under 35 U.S.C. § 102(e) as being anticipated by Robinson et al. (U.S. Patent No. 6,120,767; 1449).

Robinson et al. teach the use of CHO cells (e.g. CHO-K1 on column 11, line 59, Claims 1, 8 and 11), including vector systems of cloned heavy and light chains , including the use of selectable markers such as drug resistance and regulatory elements to produce immunoglobulins of interest, including therapeutic chimeric and CDR-grafted antibodies that bind and treat B cell disorders such as leukemia or lymphoma (see entire document, including Summary of the Invention, Detailed Description of the Invention and Claims). Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed structural and functional limitations would be inherent properties of the referenced methods of producing recombinant antibodies in stably transfected CHO cells, methods of producing said antibodies and treating cancer patients.

While it is acknowledged that the elected invention is drawn to methods of treating cancer as it reads on non-Hodgkin's lymphoma, given the applicability of this reference in the obviousness rejection, it has been applied herein under 35 U.S.C. § 102(e) as it reads on the broad claim limitations.

13. Claims 48, 49, 54, 55, 58, 59, 64, 65 and 68-85 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Robinson et al. (U.S. Patent No. 6,120,767; 1449) in view of in view of Waldmann et al. (U.S. Patent No. 5,846,534), Weidle et al. (Gene 51: 21-29, 1987; 1449), Kaetzel et al. (PNAS 82: 7280-7283, 1985; 1449) and Zettlmeissl et al. (Biotechnology 5: 720-725, 1987; 1449).

Robinson et al. teach the use of CHO cells (e.g. CHO-K1 on column 11, line 59, Claims 1, 8 and 11), including vector systems of cloned heavy and light chains , including the use of selectable markers such as drug resistance and regulatory elements to produce immunoglobulins of interest, including therapeutic chimeric and CDR-grafted antibodies that bind and treat B cell disorders such as leukemia or lymphoma (see entire document, including Summary of the Invention, Detailed Description of the Invention and Claims).

Robinson et al. differ from the claimed invention by not disclosing non-Hodgkin's lymphoma as the targeted cancer therapy as well as instantly disclosed CAMPATH-1 as the anti-cancer antibody of interest.

Waldmann et al. teach the use of generating recombinant chimeric or CDR grafted CAMPATH-1 (i.e. CDw52-specific) antibodies, including antibodies that lyse human lymphocytes with complement (e.g. columns 3-4 , overlapping paragraph) to treat various conditions or diseases, including non-Hodgkin's lymphoma (e.g. column 4, paragraph 2) (see entire document) but differ from the instant claims by not disclosing the use of CHO cells per se as the host cell of interest.

Weidle et al. teach CHO cells co-transfected with κ and γ chains with a DHFR plasmid into CHO dhfr$^-$ cells that gave rise to stable transformants that secreted functional active antibodies were known and practiced at the time the invention was made (see entire document, including the Summary)

Kaetzel et al. and Zettlmeissl et al. both teach the art known use of CHO cells to produce therapeutic proteins of interest for human therapy as well as conditions encompassed by the claimed invention of producing therapeutic proteins of interest (see entire document).

Given the teachings of Robinson et al., Weidle et al., Kaetzel et al. and Zettlemissl et al., as well as the convenience and well known economy of producing therapeutic molecules or interest recombinantly, one of ordinary skill in the art at the time the invention was made would have been motivated to select appropriate to select for CHO cells expressing therapeutic chimeric and CDR-grafted antibodies of interest, including antibodies specific for non-Hodgkin's lymphoma, including CAMPATH-1, as taught by Waldmann et al.

The selection or substitution among various equivalents known for the same purpose was obvious at the time the invention was made. For example, see MPEP 2144.06 and 2144.07.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

14. The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 48, 49, 54, 55, 58, 59, 64, 65 and 68-85 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over
claims 1, 3, 5 and 7 of U.S. Patent No. 5,545,403
claims 1 and 6 of U.S. Patent No. 5,545,404 and
claims 1, 2, 6 and 8-9 of U.S. Patent No. 5,545,405 s they read on the instantly elected invention.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to the same or nearly the same methods of treating non-Hodgkin's lymphoma with antibodies produced in CHO cells.

16. Claims 48, 49, 54, 55, 58, 59, 64, 65 and 68-85 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20, 21 and 24 on the instant elected invention of copending application USSN 09/642,826, as they read on the instantly elected invention.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to the same or nearly the same methods of treating non-Hodgkin's lymphoma with antibodies produced in CHO cells.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
November 13, 2001

DIRECTOR TC 1600